K030953

General Electric Company
P.O. Box 414, Milwaukee, WI 53201

APR 10 2003

510(k) Summary

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.92(c).

Submitter: GE Medical Systems
PO Box 414
Milwaukee, WI 53201

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Date Prepared: March 24,2003

Device Name:

GE 3.0T General Purpose Flex Coil
Magnetic Resonance Coil, 21 CFR 892.1000, 90-MOS

Marketed Device:

The GE 3.0T General Purpose Flex Coil is substantially equivalent to the currently marketed GE Medical Systems 1.5T GP Flex coil M1085GP (K923264)

Device Description:

The GE 3.0T General Purpose Flex Coil is a modification of the existing 1.5T GP Flex Coil (K923264), to increase the field strength from 1.5T to 3.0T. In addition, two passive blocking networks are added to improve reliability and patient safety.

Indications for Use:

The GE 3.0T General Purpose Flex Coil is designed to facilitate MR imaging of the Brachial Plexus, Unilateral Hip and Thigh. The GE 3.0T General Purpose Flex Coil will facilitate dynamic MR imaging of the joints of lower extremity (Knee and Ankle). This coil consists of two 5" x 6.5" surface coils coupled as a Helmholtz pair in a flexible package that can be wrapped around the anatomy of interest. This flexibility allows for the coil to be applied to a wider range of patients when compared to a similar coil in a rigid package. The coil is an option to the GE Signa® 3.0T whole body MR System.

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Comparison with Predicate Device:

The GE 3.0T General Purpose Flex Coil is a modification of the existing cleared 1.5T General Purpose Flex Coil (K923264), with the main difference being the coil has been retuned for operation in a 3.0T magnetic field instead of a 1.5T field strength. In addition, two passive blocking networks are added to improve reliability, and patient safety.

Summary of Studies:

Testing was performed to demonstrate that the design modifications to the 1.5T general Purpose Flex coil meet predetermined acceptance criteria.

Conclusion:

It is the opinion of GE that the 3.0T General Purpose Flex Coil is substantially equivalent to the GE 1.5T general Purpose Flex coil (K923264). Usage of the GE 3.0T General Purpose Flex Coil does not result in any new potential hazards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 10 2003

Larry Kroger, Ph.D.
Senior Regulatory Programs Manager
GE Medical Systems
P.O. Box 414
MILWAUKEE WI 53201

Re: K030953
Trade/Device Name: GE 3.0T General Purpose Flex Coil
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: 90 MOS
Dated: March 24, 2003
Received: March 27, 2003

Dear Dr. Kroger:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K030953

Device Name: GE 3.0T General Purpose Flex Coil

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use √ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

David A. Seaman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K030953